UNITED STATES PATENT AND TRADEMARK OFFICE

FEB 22 2007

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

PATENT DEPARTMENT
TAYLOR, PORTER, BROOKS & PHILLIPS, L.L.P
P.O. BOX 2471
BATON ROUGE, LA 70821-2471

In re Application of	:
Frederick M. Enright et al.	:
Serial No.: 10/617,561	: PETITION DECISION
Filed: July 11, 2003	:
Attorney Docket No.: 96A3.3 Enright	:

This is in response to the petition under 37 CFR 1.144, filed September 18, 2006, requesting withdrawal of an improper restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

A review of the file history shows that this application was filed on July 11, 2003, under 35 U.S.C. 111(a). The examiner mailed to applicants on May 31, 2006, a restriction requirement, wherein five distinct inventions (Groups I-V) were identified and rationale set forth establishing the examiner's position. The claims were restricted as follows:

I. Claims 1-8, 11-14, 17, 127, 129 and 130, drawn to a DNA molecule encoding a fusion peptide, classified in class 536, subclass 23.1.

II. Claims 31-41, 105-114, 120 and 122, drawn to a method for decreasing fertility in an animal, classified in class 514, subclass 12.

III. Claims 48, 59-70, 73-76, 79, 83, 86-87, 123, 125, 126 and 128, drawn to a method for killing or inhibiting the growth of a cell in a hormone-dependent or ligand-dependent tumor in a mammal, classified in class 514, subclass 12.

IV. Claims 116 and 118, drawn to a method a method for selectively reducing the number of viable gonadotrophic cells in the pituitary of an animal, classified in class 514, subclass 12.

V. Claims 131-133, drawn to a vector wherein the DNA molecule is operatively linked to an acute-phase responsive promoter, classified in class 435, subclass 320.1.

Applicants' replied on July 5, 2006, electing Group I (claims 1-8, 11-14, 17, 127, 129 and 130), with traverse. Applicants argued that restriction between Groups I-V is improper because the Office has not established that Group I is distinct from any of the other groups and has not established that a serious burden would be placed on the examiner if restriction is not required.

The examiner mailed a new Office action on August 18, 2006, acknowledging the election of Group I and the traversal. The examiner maintained the requirement and made it Final on the basis that Groups I-V were distinct and searches for the inventions were not coextensive. Claims 31-41, 48, 59-70, 73-76, 79, 83, 86-87, 105-114, 116, 118, 120, 122-126, 128 and 131-133 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 1-8, 11-14, 17, 127, 129 and 130 were rejected on the ground of nonstatutory double patenting over claims 1-109 of US 6,635,740. Claims 129 and 130 were rejected under 35 U.S.C. 101 as being drawn to non-statutory subject matter. Claims 1-8, 11-14, 17, 127, 129 and 130 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement and for containing new matter. Claims 129 and 130 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement.

Applicants filed this petition on September 18, 2006, asking review of the restriction requirement.

On February 14, 2007, a response and amendment was filed.

DISCUSSION

The petition and filed history have been carefully considered.

Applicants argue that the examiner has not demonstrated that the inventions are independent or distinct. Applicants contend that the examiner's rationale for restricting the method claims of Groups II, III and IV from the DNA sequences claims of Group I was improper (the examiner contends that the method claims of each of Groups II, III and IV were distinct from the product claims of Group I because the processes as claimed might be practiced with another, materially different product). Applicants further assert that the restriction requirement is improper because the examiner incorrectly concluded that Groups I and V are related as a product and process of use.

Applicants are correct in that inventions of Groups I-V are not independent. The inventions are "independent" (i.e., unrelated) if there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect. In the instant case, such a relationship exists between the claims of Group I and Groups II-IV. As set forth by the examiner, Groups II, III and IV are methods employing the product of Group I. The examiner's contention that Groups I and V are related as a product and method of use is incorrect. Groups V and I are related as a combination/subcombination.

Where two or more related invention are claimed, the principal question to be determined in connection with a requirement to restrict is whether or not the inventions as claimed are distinct. In applications claiming inventions in different statutory categories, only one-way distinctness is

generally needed to support a restriction requirement. See MPEP § 806.05(c) (combination and subcombination) and § 806.05(j) (related products or related processes) for examples of when a two-way test is required for distinctness. A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process. In the instant case, the product of Group I can be used: 1) in a method for decreasing fertility in an animal or 2) in a method for killing or inhibiting the growth of a cell in a hormone-dependent or ligand-dependent tumor in a mammal. Thus, product claims of Group I are distinct from the methods of Groups II, III and IV.

Groups V and I are related as a combination/subcombination. M.P.E.P. § 806.05(c) states that:

> [t]he inventions are distinct if it can be shown that a combination as claimed:
> (A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), and
> (B) the subcombination can be shown to have utility either by itself or in another materially different combination.

Although Group I has utility by itself for encoding a peptide in vitro for affinity purification of antibodies or for diagnostic testing for hormone levels, Group V requires "a DNA sequence as recited in Claim 1" and thus requires the particulars of the subcombination of Group I. Therefore, Groups I and V are not distinct and cannot be restricted.

Groups II, III and IV are drawn to related processes. To support a requirement for restriction between two or more related product inventions, or between two or more related process inventions, both two-way distinctness and reasons for insisting on restriction are necessary, i.e., separate classification, status in the art, or field of search. Related process inventions are distinct if:

> (A) the inventions as claimed do not overlap in scope, i.e., are mutually exclusive;
> (B) the inventions as claimed are not obvious variants; and
> (C) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect.

The claims of Groups II and IV are not mutually exclusive. The preamble language of the claims has been noted (method for decreasing fertility vs. method for selectively reducing the number of viable gonadotrophic cells); however, artisans of ordinary skill may not recognize the inherent characteristics or functioning of an invention. In construing process claims, it is the identity of manipulative operations which distinguishes the claims. In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps of the claims. Groups II and IV recite the same, singular methodological step of "administering to the animal an effective amount of a DNA sequence encoding a peptide, wherein said peptide comprises a first domain and a second domain...and (b) the second domain comprises a lytic peptide". Reducing fertility in the animal is not an active methodological step in the process but is rather a consequence of reducing the number of viable gonadotrophic cells in the pituitary of the animal.

Although it is not required that artisans of ordinary skill in the art recognize the inherent functions of invention, Groups II and IV are obvious variants. It would have been obvious to one of ordinary skill in the art at the time of the invention that reducing the number of viable gonadotrophic cells in the pituitary of an animal would decrease said animal's fertility as gonadotrophic cells play an important role in normal reproduction. Groups II and IV cannot be restricted.

In regards to Groups II and III, the inventions do not overlap in scope as Group III is drawn to treating a mammal having a hormone-dependent or ligand-dependent tumor. Group II does not require the mammal to have a tumor; thus, the patient populations are not coextensive. The inventions are not obvious variants. One of ordinary skill in the art at the time of the invention would not have had a reasonable expectation of success in treating a tumor by employing a method to decrease fertility or vice versa. The methods of Groups II and III also have different effects. The effect of Group II is a decrease in fertility in the mammal treated. The effect of Group III is inhibition or death of a tumor cell in the mammal treated. Thus, Groups II and III are distinct. For the same reasons, Groups III and IV are distinct.

The product of Group V is unrelated to the methods of Groups II-IV as said methods do not employ the vector of Group V; however, this point is rendered moot since Groups I and V are rejoined.

Applicants' argument that search and examination of Groups II, III and IV would not be unduly burdensome because Groups II, III and IV fall within the same class and subclass is noted. As set forth supra, Groups II and IV cannot be restricted and have been rejoined; however, searching a method for decreasing fertility in an animal and a method of killing or inhibiting the growth of a cell in a hormone-dependent or ligand-dependent tumor in a mammal are not coextensive, which would impose a serious burden on the examiner.

DECISION

The petition is **GRANTED-IN-PART** for the reasons set forth above. Groups I and V are rejoined and will be examined together. Groups II and IV are rejoined. The claims are now restricted into three groups as follows:

I. Claims 1-8, 11-14, 17, 127, 129 and 130-133, drawn to a DNA molecule encoding a fusion peptide, classified in class 536, subclass 23.1.

II. Claims 31-41, 105-114, 116, 118, 120 and 122, drawn to a method comprising administering to an animal an effective amount of a DNA sequence encoding peptide wherein said peptide comprises a first domain and a second domain, classified in class 514, subclass 12.

III. Claims 48, 59-70, 73-76, 79, 83, 86-87, 123, 125, 126 and 128, drawn to a method comprising administering an effective amount of a DNA sequence encoding peptide wherein said peptide comprises a first domain and a second domain to an animal having a hormone-dependent or ligand-dependent tumor, classified in class 514, subclass 12.

The application will be forwarded to the examiner to consider the response and amendment filed 14 February 2007 and for further action consistent with this decision.

Should there be any questions about this decision, please contact Quality Assurance Specialist/Program Manager Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

John LeGuyader
Director, Technology Center 1600
jb/pl